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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/461,829	12/15/1999	ROBERT-JAN ENZERINK	265280-64723	4338

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EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 04/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/461,829

Applicant(s)

ENZERINK ET AL.

Examiner

Brian E Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 35-39 is/are pending in the application.
- 4a) Of the above claim(s) 7-15, 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 35, 36, 38 and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Continued Prosecution Application

The request filed on 1/17/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/461829 is acceptable and a CPA has been established. An action on the CPA follows.

Election/Restrictions

This application contains claims directed to the following patentably distinct species of the claimed invention:

Species I: Figs. 1-3.

Species V: Fig. 10.

Species II: Figs. 4-6.

Species VI: Figs. 11, 12.

Species III: Fig. 7.

Species VII: Fig. 13.

Species IV: Figs. 8, 9.

Species VIII: Fig. 14.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 35 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and *a listing of all claims readable thereon*, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Susanne Hopkins on 4/4/02 a provisional election was made without traverse to prosecute the invention of Species IV, claims 1-6,35,36,38,39. Affirmation of this election must be made by applicant in replying to this Office action. Claims 7-15,37 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-6, 35,36,38,39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear as to whether the sutures are "attached sutures" or "pre-attached sutures" *prior to* implantation or *prior to* preservation and sterilization inserted into a package or kit. For example, claim 1 recites, "wherein the **graft** is preserved and provided in sterile packaging". This does not necessarily imply that the sutures are already attached. In claim 35, the preamble recites a "kit" and in the kit is "pre-attached sutures" which can be interpreted that these sutures in the kit are intended to be attached *prior to* implantation, thus considered as "pre-attached sutures."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 as best understood, are rejected under 35 U.S.C. 102(b) as being anticipated by McGuire (5562669). McGuire discloses that allografts can be used as replacement ligaments, col. 6, lines 32-42. McGuire discloses to have sutures attached

at a proximal end and distal end and include using semitendinosis and gracilis tendons, col. 5, lines 1-11 and col. 6, lines 60-61. McGuire also discloses the sutures are attached **prior to** implantation to aid in insertion, col. 5, lines 54-62. McGuire additionally discloses preserving grafts that are used for future ligament replacement procedures, col. 6, lines 34-36. It is inherent the preserved graft would be sterilized and packaged. The graft can be a bundle of strands, col. 6, lines 60-61.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 35, 36, 38 as best understood, are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McGuire '669. McGuire is explained supra. McGuire additionally discloses that fixation devices are used in "kits" for ligament repair, col. 5, lines 17-22. Because the individual components of applicant's claimed kit *for ligaments* are known in the prior art, it can be construed that any type of combination of these components available at the same time form a "kit". Since the sutures are pre-attached prior to surgery, it can be construed that the claim limitations are met. It is inherent that the components are sterile before the surgery, as any medical surgery would require sterile items.

However, in the alternative, McGuire does not disclose a kit with sutures attached to the graft prior to sterilizing and packaging. Dumican et al. (4987665) teach ligament grafts are packaged and sterilized with pre-attached sutures, col. 11, lines 34-41. It would have been obvious to one of ordinary skill in the art to have pre-attached

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sutures with the graft ligament of McGuire in order to save time in the surgery that would be required if the sutures were placed in the ligament while conducting the surgery.

Claims 5, 6, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuire '669 in view of Schmieding '561. McGuire is explained supra. However, McGuire does not disclose the use of long strand sutures and various lengths of ligaments. Schmieding teaches that long strand sutures are placed on the graft to aid in placement in a patient, col. 5, lines 25-32. Schmieding also teaches to use various lengths for ligament repairs, col. 4, lines 56-66. It would have been obvious to one of ordinary skill in the art to provide various lengths of ligaments and use long sutures as taught by Schmieding for the graft of McGuire in order to provide the proper length necessary for the patient and have sufficient suture to secure it in place.

Response to Arguments

Applicant's arguments filed 1/17/02 have been fully considered but they are not persuasive. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., sutures being preserved and packaged with the graft in addition to being attached) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In view of the new

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112 2nd paragraph rejections, the McGuire reference can be interpreted to read on the claims as presented.

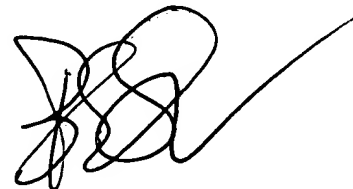
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 9am to 6:30pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Brian E. Pellegrino
April 4, 2002



Bruce Snow
Primary Examiner
TC 3700, AU 3738